



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number RegGuide, 509 Tower Valley Drive, Hillsboro, MO 63050 (636) 942-2583	EPA Registration Number/File Symbol 74896- 5
Active Ingredient(s) and/or representative test compound(s) Oxytetracycline Hydrochloride	Date January 16, 2003
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food & Non-Food, Greenhouse Food & Non-Food, Forestry; Aquatic Non-Food	Product Name RG OTC Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

01-16-03

Sharon M. Johnston / President




Form Approved OMB No. 2070-0060

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DATA MATRIX

Date January 16, 2003		EPA Reg No./File Symbol 74896-		Page 1 of 9	
Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical			
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1	Chemical Identity		RegGuide	OWN	
61-2	Beginning Materials & Manufacturing Process		RegGuide	OWN	
61-3	Discussion of Formation of Impurities		RegGuide	OWN	
62-1	Preliminary Analysis		RegGuide	OWN	
62-2	Certification of Ingredient Limits		RegGuide	OWN	
62-3	Analytical Method to Verify Certified Limits		RegGuide	OWN	
63-2	Color		RegGuide	OWN	
63-3	Physical State		RegGuide	OWN	
64-4	Odor		RegGuide	OWN	
63-6	Boiling Point				NA - Solid
63-7	Density, Bulk Density or Specific Gravity		RegGuide	OWN	
Signature 			Name and Title Sharon M. Johnston President		Date January 16, 2003



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DATA MATRIX

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Applicant's/Registrant's Name & Address


RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Product

RG OTC Technical

Ingredient

Oxytetracycline Hydrochloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-8	Solubility		RegGuide	OWN	
63-9	Vapor Pressure		RegGuide	OWN	
63-10	Dissociation Constant		RegGuide	OWN	
63-11	Octanol/Water Partition Coefficient		RegGuide	OWN	
63-12	pH		RegGuide	OWN	
63-13	Stability		RegGuide	OWN	
63-17	Storage Stability		RegGuide	OWN	
63-20	Corrosion Characteristics		RegGuide	OWN	
Signature			Name and Title	Sharon M. Johnston President	Date January 16, 2003

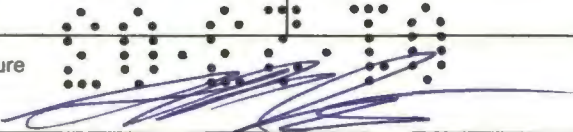


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Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050			Product RG OTC Technical		
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
71-1	Acute Avian Oral Toxicity - Quail & Duck	Cite All	See attached data submitters list	PAY	
71-2(a)	Acute Avian Dietary Toxicity - Quail	Cite All	See attached data submitters list	PAY	
71-2(b)	Acute Avian Dietary Toxicity - Duck	Cite All	See attached data submitters list	PAY	
71-4(a)	Avian Reproduction - Quail	Cite All	See attached data submitters list	PAY	
71-4(b)	Avian Reproduction - Duck	Cite All	See attached data submitters list	PAY	
72-1(a)	Freshwater Fish Toxicity (TGAI)	Cite All	See attached data submitters list	PAY	
72-1(b)	Freshwater Fish Toxicity (TEP)	Cite All	See attached data submitters list	PAY	
72-2(a)	Invertebrate Toxicity (TGAI)	Cite All	See attached data submitters list	PAY	
72-2(b)	Invertebrate Toxicity (TEP)	Cite All	See attached data submitters list	PAY	
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Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical			
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1	Acute Oral Toxicity	Cite All	See attached data submitters list	PAY	
81-2	Acute Dermal Toxicity	Cite All	See attached data submitters list	PAY	
81-3	Acute Inhalation Toxicity	Cite All	See attached data submitters list	PAY	
81-4	Primary Eye Irritation	Cite All	See attached data submitters list	PAY	
81-5	Primary Dermal Irritation	Cite All	See attached data submitters list	PAY	
81-6	Dermal Sensitization	Cite All	See attached data submitters list	PAY	
81-8	Acute Mammalian Neurotoxicity	Cite All	See attached data submitters list	PAY	
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Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical			
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
82-1(a)	90-Day Feeding Study - Rat	Cite All	See attached data submitters list	PAY	
82-1(b)	90-Day Feeding Study - Dog	Cite All	See attached data submitters list	PAY	
82-2	28-Day Dermal Toxicity - Rat	Cite All	See attached data submitters list	PAY	
82-4	28-Day Inhalation Toxicity - Rat	Cite All	See attached data submitters list	PAY	
83-1(b)	Chronic Feeding Study - Dog	Cite All	See attached data submitters list	PAY	
83-2	Oncogenicity Study - Mouse	Cite All	See attached data submitters list	PAY	
83-3(a)	Developmental Toxicity - Rat	Cite All	See attached data submitters list	PAY	
83-3(b)	Developmental Toxicity - Rabbit	Cite All	See attached data submitters list	PAY	
83-4	2-Generation Reproduction Study - Rat	Cite All	See attached data submitters list	PAY	
83-5	Combined Chronic Feeding/Oncogenicity Study - Rat	Cite All	See attached data submitters list	PAY	
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Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
84-2	Gene Mutation (Ames Assay)	Cite All	See attached data submitters list	PAY	
84-2	Structural Chromosomal Aberration	Cite All	See attached data submitters list	PAY	
84-4	Other Genotoxic Effects	Cite All	See attached data submitters list	PAY	
85-1	General Metabolism - Rat	Cite All	See attached data submitters list	PAY	
85-3	Dermal Absorption	Cite All	See attached data submitters list	PAY	
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Applicant's/Registrant's Name & Address RegGuide 509 Tower Valley Drive Hillsboro, MO 63050		Product RG OTC Technical			
Ingredient Oxytetracycline Hydrochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
141-1	Honeybee Acute Contact LD50	Cite All	See attached data submitters list	PAY	
141-2	Honeybee Toxicity from Residue on Foliage	Cite All	See attached data submitters list	PAY	
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Applicant's/Registrant's Name & Address


RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Product

RG OTC Technical

Ingredient

Oxytetracycline Hydrochloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
161-1	Hydrolysis	Cite All	See attached data submitters list	PAY	
161-2	Photodegradation - Water	Cite All	See attached data submitters list	PAY	
162-1	Aerobic Soil Metabolism	Cite All	See attached data submitters list	PAY	
162-2	Anaerobic Soil Metabolism	Cite All	See attached data submitters list	PAY	
163-1	Leaching & Adsorption/Desorption	Cite All	See attached data submitters list	PAY	
163-2	Lab Volatility	Cite All	See attached data submitters list	PAY	
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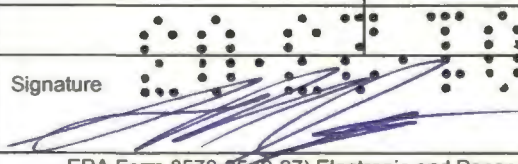
RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Product

RG OTC Technical

Ingredient

Oxytetracycline Hydrochloride

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(a)	Nature of the Residue – Plant Metabolism	Cite All	See attached data submitters list	PAY	
171-4(k)	Magnitude of the Residue – Crop Field Trials	Cite All	See attached data submitters list	PAY	
171-4(l)	Magnitude of the Residue – Processed Food	Cite All	See attached data submitters list	PAY	
Signature			Name and Title Sharon M. Johnston President		Date January 16, 2003

CHEMICAL CHEMICAL NAME

006308 Oxytetracycline hydrochloride

COMPANY# 001007 PFIZER INC

D/B/A PFIZER ANIMAL HEALTH, ATTN: JOHN B

* DATA TYPES * 601 WEST CORNHUSKER HIGHWAY

EU AT EC FW EF OT LINCOLN NE

XX XX 68521

COMPANY# 066607 SPRAY DRIFT TASK FORCE

MCKENNA & CUNEO L.L.P

* DATA TYPES * 1900 K STREET, NW

EU AT EC FW EF OT WASHINGTON DC

XX 20006

COMPANY# 071754 BEVERIDGE & DIAMOND, P.C.

AGENT FOR: OUTDOOR RESIDENTIAL EXPOSURE

* DATA TYPES * 1350 I STREET, N.W.

EU AT EC FW EF OT WASHINGTON DC

XX 20005

